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IN THE

Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-528

CIBA CORPORATION, a corporation of the State of Delaware,
Petitioner,

vs.

ELLIOTT L. RICHARDSON, Secretary of Health, Education & Welfare and DR. CHARLES C. EDWARDS, Commissioner of Food and Drugs,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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TABLE OF CONTENTS

	PAGE
Opinions Below	1
Jurisdiction	1
Question Presented	2
Statute Involved	2
Statement of the Case	2
Reasons for Granting the Writ	4
Conclusion	9

INDEX TO AUTHORITIES

CASES

Bentex Pharmaceuticals Inc. v. *Richardson*, —— F. 2d ——, CCH Food Drug and Cosmetic Law Reporter ¶ 40,665 (4th Cir. 1972)	6, 7
Merritt Corp. v. *Folsom*, 165 F. Supp. 418 (D.D.C. 1958)	8
United States v. *Allan Drug Corp.*, 357 F. 2d 713 (10th Cir. 1966)	8
United States v. *An Article of Drug . . . "Excedrin," P.M.*, —— F. Supp. ——, CCH, Food Drug and Cosmetic Law Reporter ¶ 40,486 (E.D.N.Y. 1971)	8
United States v. *An Article of Drug . . . "Furestrol,"* 294 F. Supp. 1307 (D. Ga. 1968) affirmed 415 F. 2d 390 (5th Cir. 1969)	8

PAGE

U.S. v. *An Article of Drug . . . "Line Away,"* 284 F. Supp. 107 (D. Del. 1968) affirmed other grounds 415 F. 2d 369 (3rd Cir. 1969) 8

United States v. *An Article of Drug . . . Quinaglute,* 268 F. Supp. 245 (E.D.Mo. 1967) 8

United States v. *Articles of Drug . . . Quick-O-Ver,* 274 F. Supp. 443, 445-46 (D.Md. 1967) 8

U.S. v. *7 Cartons . . . "Ferro-Lac,"* 293 F. Supp. 660 (S.D. Ill. 1968) affirmed 424 F. 2d 1364 (7th Cir. 1970) 8

United States v. *345 Bulk Cartons • • • "Trim Reducing Aid Cigarettes,"* 178 F. Supp. 847 (D.N.J. 1959) 8

USV Pharmaceuticals v. *Richardson,* 461 F. 2d 223 (4th Cir. 1972) 7

STATUTES

21 U.S.C. 321 (p) (1938), as amended 1a

21 U.S.C. 331 (d) (1938) 4, 1a

21 U.S.C. 332 (a) (1938, as amended) 2a

21 U.S.C. 333 (a) (1938, as amended) 2a

21 U.S.C. 334 (a) (1938, as amended) 2a

21 U.S.C. 355 (a) (1938, as amended) 3a

21 U.S.C. 355 (d) (1938, as amended) 5, 3a

21 U.S.C. 355 (e) (1938, as amended) 4a

21 U.S.C. 355 (h) (1938, as amended) 5a

76 Stat. 780 (1962) 3

FDA REGULATIONS

21 CFR, Part 130, § 130.12 5

INDEX TO APPENDIX

PAGE

Text of Pertinent Sections of the Food, Drug and Cosmetic Act 1a

Text of Order and Opinion of Third Circuit Court of Appeals 7a

Text of Opinion of Fourth Circuit Court of Appeals in *Bentex Pharmaceuticals Inc.* vs. *Richardson* 11a

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Opinions Below

The opinion of the Court of Appeals appears at —— F. 2d ——, CCH Food Drug and Cosmetic Law Reporter ¶40,676 (3rd Cir. 1972) and in the appendix hereto, *infra*, at 9a. The oral opinion of the District Court did not consider the issues raised herein and, by stipulation of the parties, has not been reprinted.

Jurisdiction

The judgment and opinion of the Court of Appeals were entered on June 5, 1972. By order signed by Justice Rehnquist of this Court dated September 1, 1972, the time for filing a petition for a writ of certiorari herein was extended to October 2, 1972. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

Question Presented

Do the Federal district courts have exclusive jurisdiction to adjudicate whether a drug is a "new drug" as defined in the Food, Drug and Cosmetic Act of 1938, as amended, and therefore subject to the regulatory proceedings applicable to such drugs?

Statute Involved

The statute involved is The Food Drug and Cosmetic Act of 1938, as amended, 21 U.S.C. § 301 *et seq.* The pertinent sections of that Act are set forth in the appendix hereto, *infra,* at p. 1a *et seq.*

Statement of the Case

The Federal Food, Drug and Cosmetic Act of 1938,[1] as amended (the "Act"), provides that certain drugs called "new drugs" may not be shipped in interstate commerce without prior, formal Food and Drug Administration (the "FDA") approval granted on the basis of information submitted as part of a New Drug Application. A New Drug Application for Ritonic, the drug which is the subject of this action, became effective on January 12, 1958. At that time, the Act required such Applications to contain evidence demonstrating that the drug was *actually* safe for the conditions of use recommended or prescribed in its

[1] 21 U.S.C. § 301 *et seq.*

labeling. The Act also provided at that time that a drug was not a "new drug" if it was *generally recognized* as safe for the conditions of use recommended or prescribed in its labeling.

In 1962 the Act was amended[2] so as to, *inter alia*, make approval of a New Drug Application dependent upon the production of specified evidence of effectiveness as well as safety. In addition, the definition of a "new drug" was expanded to also include drugs not generally recognized as effective. As a result of these amendments, the FDA contracted with the National Academy of Sciences-National Research Council (the "NAS-NRC" for the review of drugs subject to New Drug Applications prior to 1962 to determine whether there existed for such drugs the requisite evidence of their effectiveness.

On September 30, 1970, after an exchange of several communication between Ciba and the FDA, the FDA published in the Federal Register a notice[3] denying Ciba's request for a hearing and withdrawing, based on a finding by an NAS-NRC panel of a lack of the requisite evidence of effectiveness, the New Drug Application previously in effect for Ritonic.

In response to the FDA's withdrawal of the New Drug Application for Ritonic, Ciba filed this action seeking a declaration that Ritonic is not a "new drug" and therefore legally marketable without an approved New Drug Application.[4]

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[2] 76 Stat. 780 (1962)

[3] Vol. 35, No. 190

[4] Ciba also filed a direct appeal under § 505(h) of the Act from that portion of the FDA's order refusing Ciba's request for an administrative hearing to review the adequacy of the evidence submitted in support of the New Drug Application for Ritonic, and the denial of a hearing was affirmed. *Ciba-Geigy Corporation* v. *Richardson*, 446 F. 2d 466 (2nd Cir. 1971). The Second Circuit action did not in any way consider and, for the reasons indicated hereinafter, could not have considered the "new drug" status of Ritonic.

Respondents moved to dismiss the complaint on the ground, *inter alia*, that the FDA, not the courts, has exclusive jurisdiction to determine whether a drug is a "new drug" and that a manufacturer's only avenue of judicial redress from an FDA determination on this point is by way of appeal to a circuit court of appeals. By stipulation of the parties, this jurisdictional question was the sole issue briefed or argued in either of the courts below.

The district court held the jurisdictional issue to be moot and dismissed the action on the ground that even if the court had jurisdiction it would exercise its discretion and refuse to determine whether Ritonic was a "new drug" in a declaratory judgment action. The Third Circuit Court of Appeals affirmed the dismissal on the ground that the FDA has jurisdiction to adjudicate whether a drug is a "new drug" and that the FDA properly exercised that jurisdiction in its administrative proceeding withdrawing the New Drug Application previously in effect for Ritonic.

Ciba seeks a writ of certiorari to establish that, under the Act, the district courts have exclusive jurisdiction to determine whether a particular drug is a "new drug" and therefore subject to the "new drug" procedures.

Reasons for Granting the Writ

The Act provides that before a manufacturer may ship a "new drug" in interstate commerce it must obtain FDA approval of a New Drug Application for that drug.[5] The FDA is instructed to issue an order denying approval of a New Drug Application[6] or withdrawing approval previously granted[7] if the Commissioner concludes that there is a lack of "substantial evidence" that the drug involved is

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[5] Act § 301(d) which incorporates by reference § 505(a); 21 U.S.C. 331(d), 355(a); Appendix pps. 1a, 3a

[6] Act § 505(d); 21 U.S.C. 335(d); Appendix p. 3a

[7] Act § 505(e); 21 U.S.C. 355(e); Appendix p. 4a

safe and effective for the conditions of use prescribed or recommended in its labeling.

"Substantial evidence" is a term of art defined in the Act and the regulations promulgated thereunder[8] as, in essence, the results of "adequate and well-controlled clinical investigations by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have . . . [in its labeling.]"

Not all drugs, however, are required to have an approved New Drug Application before they can be marketed; only "new drugs" must follow this procedure. The term "new drug" is also a term of art defined in the Act.[9] In essence a "new drug" is any drug which is not generally recognized by experts qualified to evaluate the safety and effectiveness of drugs as being safe and effective for the conditions of use recommended in its labeling or any drug which is so recognized but which has not been used to a material extent or for a material time for the conditions recommended in its labeling.

The distinction between whether a drug is a "new drug", *i.e.*, generally recognized as safe and effective, and not required to have a New Drug Application, and whether a "new drug" has been demonstrated by "substantial evidence" to be safe and effective and therefore entitled to approval of its New Drug Application is part of the basic structure of the Act. If a drug has been in use by the medical profession for a material time and to a material extent and if, through such use, has become generally recognized as being safe and effective, then the drug is no longer a "new drug" and the manufacturer may market it

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[8] Act § 505(d); 21 U.S.C. 355(d); Appendix p. 3a; 21 CFR, Part 130, § 130.12

[9] Act § 201(p); 21 U.S.C. 321(p); Appendix p. 1a

without it being the subject of an approved New Drug Application.

Respondents do not dispute that drugs which are not "new drugs" may be legally marketed without an approved New Drug Application; they argue, rather, that the FDA rather than the district courts has jurisdiction of the "new drug" question and that when the FDA has made a determination of this question with respect to a particular drug the only judicial remedy is an appeal from the FDA's action to an appropriate court of appeals.

The court below, without citation of authority, accepted the position of the respondents. It did so by concluding that the FDA's jurisdiction to determine whether a drug is a "new drug" is implicit in that agency's jurisdiction to determine whether a "new drug" is entitled to New Drug Application approval. That conclusion is not only devoid of judicial support but also is without cited statutory authority.

Administrative agencies cannot restrict the rights of those regulated unless such jurisdiction or authority is expressly conferred by statute. Section 505 of the Act establishes the power in the FDA to regulate "new drugs". Nowhere in that section, or in any other section of the Act, is the agency authorized to adjudicate the issue of whether a drug or is not a "new drug". The procedure established in Section 505 of the Act contemplates only the adjudication of whether the tests for approval of a New Drug Application, *i.e.* "substantial evidence" of safety and effectiveness, have been met.

In sharp contrast to the conclusion of the court below, the Court of Appeals for the Fourth Circuit, in *Bentex Pharmaceuticals, Inc.* v. *Richardson,* —— F. 2d ——, CCH Food Drug and Cosmetic Law Reporter ¶ 40,665 (4th Cir. 1972), appendix hereto, *infra,* p. 11a, rejected the argu-

ment of the FDA advanced below and concluded that the FDA was without jurisdiction to determine whether a drug is a "new drug"[10].

The *Bentex* case, like the instant one, was a declaratory judgment action commenced by a manufacturer seeking a determination that its product was not a "new drug". The manufacturer in *Bentex*, like Ciba, acted after receiving notice from the FDA that it had determined its product to be a "new drug" which lacked an approved New Drug Application and that consequently the FDA would institute enforcement proceedings if the drug was not withdrawn from the market. In *Bentex* the FDA argued, as it did below, that the district courts lack jurisdiction to adjudicate the "new drug" status of drugs

The Fourth Circuit concluded that the questions of whether to grant approval of a New Drug Application and whether a drug is a "new drug" are wholly separate and distinct. After an analysis of the Act, it held that there was no basis for concluding that the FDA had jurisdiction to adjudicate the latter question or that the Court of Appeals would have jurisdiction on appeal to review such a determination if it were made.

This conclusion of the Fourth Circuit is consistent with the historic position of the FDA. As that court noted, the FDA has not, until recent times, ever claimed jurisdiction to determine the issue of whether a product is or is not a "new drug".

The conflict in the circuits on the jurisdictional issue is one which should be promptly resolved by this Court. The determination of whether a drug is a "new drug" or not is ofttimes determinative of whether a manufacturer may continue to market the product. The economic impact of this issue is thus obvious.

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[10] See also *USV Pharmaceuticals Corp.* v. *Richardson*, 461 F. 2d 223 (4th Cir. 1972)

The efficient administration of one of the nation's most important regulatory acts has, as a result of the conflict in the circuit opinions, been substantially impaired. Is it for the FDA to adjudicate whether a drug is a "new drug"? If so, as the Third Circuit concludes, that adjudication will take place in a forum where the FDA acts both as prosecutor and judge. It is submitted that there is no basis for that conclusion, and that that issue, as held by the Fourth Circuit, is one which is to be decided in an impartial judicial forum. That result is supported not only by the provisions of the Act but also by the substantial body of law developed in the district courts since the passage of the Act. See *e.g.*, *Merritt Corp.* v. *Folsom*, 165 F. Supp. 418 (D.D.C. 1958); *U.S.* v. *354 Bulk Cartons* • • • *"Trim Reducing Aid Cigarettes"*, 178 F. Supp. 847 (D.N.J. 1959); *U.S.* v. *An Article of Drug . . . Quinaglute*, 268 F. Supp. 245 (E.D.Mo. 1967); *U.S.* v. *Articles of Drug . . . Quick-O-Ver*, 274 F. Supp. 443, 445-46 (D.Md. 1967); *U.S.* v. *An Article of Drug . . . "Line Away"*, 284 F. Supp. 107 (D. Del. 1968) affirmed other grounds 415 F.2d 369 (3rd Cir. 1969); *U.S.* v. *7 Cartons . . . "Ferro-Lac"*, 293 F. Supp. 660 (S.D. Ill. 1968) affirmed 424 F. 2d 1364 (7th Cir. 1970); *U.S.* v. *An Article of Drug . . . "Furestrol"*, 294 F. Supp. 1307 (D. Ga. 1968) affirmed 415 F.2d 390 (5th Cir. 1969); *U.S.* v. *An Article of Drug . . . Excedrin P.M.*, —— F. Supp. ——, CCH, Food Drug and Cosmetic Law Reporter ¶ 40,486 (E.D.N.Y. 1971). See also *U.S.* v. *Allan Drug Corp.*, 357 F.2d 713 (10th Cir. 1966).

Conclusion

For the foregoing reasons it is respectfully submitted that the writ of certiorari requested hereby should be issued and the opinion and judgment of the Third Circuit Court of Appeals reversed.

Respectfully submitted,

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Date: September 29, 1972

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